

Exhibit A

COVINGTON

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG
LONDON LOS ANGELES NEW YORK PALO ALTO
SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 6000

By Email

February 24, 2023

Casey M. Preston
Gary L. Azorsky
COHEN MILSTEIN SELLERS & TOLL PLLC
100 N. 18th Street, Suite 1820
Philadelphia, PA 19103
cpreston@cohenmilstein.com
gazorsky@cohenmilstein.com

Theodore J. Leopold
Leslie M. Kroeger
Diana L. Martin
Poorad Razavi
COHEN MILSTEIN SELLERS & TOLL PLLC
11780 U.S. Highway One, Suite N500
Palm Beach Gardens, FL 33408
tleopold@cohenmilstein.com
lkroeger@cohenmilstein.com
dmartin@cohenmilstein.com
prazavi@cohenmilstein.com

**Re: *United States ex rel. Long v. Janssen Biotech, Inc.* –
Relator's Responses to Janssen's Second Set of
Interrogatories**

Dear Counsel:

We write to follow up on our February 13 meet and confer and to explain, in writing, the issues we identified with Relator's Objections and Responses to Janssen's Second Set of Interrogatories. This letter, along with our discussion, describes various deficiencies in Relator's responses. Please respond to this letter or supplement your interrogatory responses to address the below deficiencies by March 10, 2023.

Interrogatory 6: Identify each instance in which You provided in-office infusion support services to any Phase One Account, including (i) the date on which You provided the in-office infusion support service(s); (ii) the Phase One Account to which You provided the service(s); and (iii) the in-office infusion support service(s) provided.

As we stated during the meet and confer, the response to Interrogatory 6 does not answer the question asked. We asked Ms. Long to identify the instances in which she provided

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 2

IOI support services to Phase One Accounts, and what services she provided in each of those instances. The response does not identify any specific instances in which Ms. Long provided IOI support services to Phase One accounts. Instead, it directs us to Relator's response to Interrogatory 2, which lists documents produced by Janssen regarding Janssen's provision of IOI support services. The majority of the documents cited in Relator's response to Interrogatory 2 do not contain information responsive to this interrogatory. For example, many of the documents consist of program invitations, high-level summaries of ABS services provided nationwide, and ABS work plans and analyses, which do not indicate when relevant IOI support services were actually delivered by Ms. Long—to whom Interrogatory 6 specifically relates—to Phase One Accounts. These documents do not sufficiently address the interrogatory.

In short, the response is deficient because it responds with information about Relator's supposed understanding of what Janssen—not Ms. Long—did.

As we explained during our meet and confer, the interrogatory asks Ms. Long to identify when she provided IOI support services to Phase One Accounts and what services she provided, based on her own records and recollection. To be clear, we are not asking you to review and summarize Janssen's business records. We are asking you to identify what Ms. Long knows about her provision of IOI support services to Phase One Accounts, independent of Janssen's documents. Ms. Long made detailed allegations in her complaint about instances in which she provided IOI support services to Phase One Accounts, so we know she has information that is responsive to this interrogatory.

Please amend your response to provide the information known to Ms. Long about each instance in which she provided IOI support services to a Phase One Account, including (i) the date she provided the IOI support service; (ii) the account to which she provided the service; and (iii) the IOI support service provided. If Ms. Long has no independent record or recollection of instances in which she provided IOI support services to Phase One Accounts, please make that clear in your response.

Interrogatory 7: Identify each Phase One Account to which You provided in-office infusion support services that you believe opened up an in-office infusion suite as a result of the services You provided.

As an initial matter, during the February 13 meet and confer, we explained that we did not understand the distinction between the practices listed in the first section of Ms. Long's response to Interrogatory 7 and the practices listed in the second section of Ms. Long's response. You confirmed that the first list of practices are those that Relator believes opened an initial in-office infusion suite after receiving IOI support from Janssen and the second list of practices are those that opened a new in-office infusion suite at a different location after receiving IOI support from Janssen. Please confirm that is the case.

We next explained that the response to Interrogatory 7 is deficient because it does not answer the question asked. We asked Ms. Long to identify Phase One Accounts that she believes opened up an IOI suite ***“as a result”*** of the IOI support services that she provided. Your answer fails to address this portion of the question. Instead, it merely lists practices that Ms.

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 3

Long “advised, educated, and/or assisted.” To be clear, we are not asking Ms. Long to step into the shoes of the practices and speculate as to their state of mind. However, we are entitled to information about Ms. Long’s state of mind. Your response does not address whether Ms. Long believes the services she provided caused the accounts to open an IOI suite (whether for the first time or as an additional IOI suite).

Please amend your response to list the accounts that Ms. Long believes opened up an IOI suite **as a result** of the IOI support services she provided.

Interrogatory 8: Identify and describe each communication You had, including with employees of Defendant, in which you discussed, or raised concerns about, the legality of in-office infusion support services, prior to February 19, 2016. In your response, include (i) the date of each communication and (ii) the name of the individual(s) with whom You communicated.

Again, Ms. Long’s response to Interrogatory 8 does not answer the question asked. We asked Ms. Long to identify and describe each communication, prior to February 19, 2016, in which she discussed or raised concerns about the legality of “in-office infusion support services.” Instead, the response states that Ms. Long does not recall having any communications before February 19, 2016, in which she discussed or raised concerns about the legality of “the presentations and programs identified in her response to Interrogatory 2.” As we said during our meet and confer, we want to confirm that you are not drawing a distinction between the legality of “the presentations and programs” and the legality of “in-office infusion support services.”

Please amend your response to identify communications, prior to February 19, 2016, in which Ms. Long discussed or raised concerns about the legality of “in-office infusion support services,” or state that there were no such communications.

Interrogatory 9: Identify when you first determined that Defendant’s provision of in-office infusion support services was illegal, and explain what led you to hold that belief.

Ms. Long did not provide a response to Interrogatory 9. We asked for two pieces of information: (1) when Ms. Long first determined that Janssen’s provision of IOI support services was illegal and (2) what led Ms. Long to hold that belief. You do not provide either. Instead, you object on the grounds that the information sought is protected by the attorney-client privilege and not relevant to any claim or defense asserted in this action. Your objections are not a sufficient basis for refusing to respond to the interrogatory.

First, the date that Ms. Long first determined that the provision of IOI support services was illegal is not privileged, and it is undeniably relevant and certainly discoverable.

Second, the event, action, or communication that led Ms. Long to determine the services were illegal may or may not be privileged. If it is not privileged, it is clearly discoverable and we are entitled to that information. If it is privileged, Ms. Long must assert the privilege specifically—not as an objection that the information could be privileged.

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 4

Please amend your response to state both (1) the date that Ms. Long first determined that Janssen's provision of IOI support services was illegal and (2) what led Ms. Long to hold that belief. If "what led Ms. Long to hold [the] belief" that the provision of IOI support services was illegal were conversations with attorneys or other privileged communications, you should assert that in your response.

Interrogatory 10: Identify all remuneration conferred on the Phase One Accounts by Defendant that You allege was a kickback.

Your response, which refers back to your response to Interrogatory 2, is vague and ambiguous. Based on your response, we interpret your position to be that (1) every presentation of a program identified in your response to Interrogatory 2 that was provided to a Phase One Account was a kickback, and (2) you are not alleging that anything other than the presentations and services described in your response to Interrogatory 2 was illegal remuneration.

Please confirm that our understanding is correct. If it is not, please clarify your position.

Furthermore, the insufficiency of your response to this interrogatory is linked to the insufficiency of your response to Interrogatory 6. In Interrogatory 6, we asked for (i) the date on which You provided the in-office infusion support service(s); (ii) the Phase One Account to which You provided the service(s); and (iii) the in-office infusion support service(s) provided. Your answer to Interrogatory 10 should, at a minimum, indicate whether you allege the specific activities on specific dates identified in response to Interrogatory 6 constituted "remuneration conferred on the Phase One Accounts that You allege was a kickback."

Interrogatory 11: State the basis for Your contention that the remuneration identified in Your response to Interrogatory No. 10 was a kickback.

Your response to Interrogatory 11 is not compliant with the Court's rules for contention interrogatories. As you know, under Local Rule 26.5(c)(8), when an interrogatory asks a party to "state the basis" for a contention, the responding party must identify every document, communication, act or omission, and additional fact that is a source of the party's information regarding the alleged fact or conclusion. L.R. 26.5(c)(8). Thus, here, Local Rule 26.5(c)(8) requires you to identify every document, communication, act or omission, and additional fact that is a source for your contention that every presentation of a program identified in your response to Interrogatory 10 (or Interrogatory 2) to a Phase One Account was a kickback.

To be clear, we are not asking you for a memorandum about your case strategy. However, under the Local Rules, we are entitled to a response that completely identifies the remuneration you contend was a kickback and the factual basis—in light of the current state of discovery—for your contention. Your response does not provide this information. The first part of your response is not responsive to the interrogatory, as it is merely a recitation of cases interpreting the Anti-Kickback Statute. The next part of your response claims to be a list of "alleged facts" that you say support your allegations that IOI support services for Remicade and Simponi ARIA constituted kickbacks, but the "alleged facts" are not facts. Instead, they are vague categories of information on which you may rely. You have not, as the Local Rule

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 5

requires, provided any citations or specific examples for the “alleged facts” you list. For example, you state that your assertion that the services were a kickback is supported by “Statements and feedback from the recipients,” but you fail to identify any statements, documents containing the statements, or even the identities of any of the non-disclosed “recipients” on which you apparently intend to rely, as required. You then list “Statements by Janssen’s employees and agents,” but again fail to identify the statements, documents containing the statements, or even a single name of one of the “employees and agents.”

As you have argued to the Court, and as the Court has agreed, Local Rule 26.5(c)(8) requires a party to provide full answers to interrogatories that identify the documents and evidence that support a contention. ECF No. 307 at 5; ECF No. 322 at 10-12. Contrary to your statement during the meet and confer that this level of detail is only required for the identification of potential witnesses, your position in the past has been that it is required for all contention interrogatories, including ones that you have propounded seeking the factual bases of Janssen’s affirmative defenses. To comply with Local Rule 26.5(c)(8), you need to set forth the specific documents and communications supporting your claims.

Please amend your response to provide all of the information required by the Local Rule.

Interrogatory 12: Identify all False Claims that you allege Defendant caused the Phase One Accounts to submit to Medicare for the reimbursement of Remicade and Simponi ARIA.

Your response to Interrogatory 12 does not answer the question asked. We asked you to identify the allegedly false claims that Defendant caused to be submitted by Phase One Accounts. While the response points us to the Medicare claims data from CMS and says the claims are included in that data, it does not actually identify any claims or provide enough information about which claims are allegedly false for us to locate them.

The claims that Ms. Long alleges were false are at the heart of Ms. Long’s case. It is the responsibility of Ms. Long—not Janssen—to identify the specific false claims that are the premise for her lawsuit. Instead, you object on the grounds that it would be burdensome to ascertain the answer, which could be derived from examining millions of rows of data. That is not appropriate here, where only you can identify which claims meet the vague, incomplete criteria provided by the response.

Based on the response, we interpret your position to be that every claim for payment for Remicade, Simponi ARIA, and for the infusion of those drugs submitted by a Phase One Account to Medicare after October 28, 2010 is false, as long as Janssen provided the account with one or more of the IOI support services identified in your response to Interrogatory 2 at least one time before October 28, 2010. For Phase One Accounts for which Janssen did not provide at least one IOI support service before October 28, 2010, false claims are measured from the date that Janssen first provided the account with an IOI support service identified in your response to Interrogatory 2 to the present. As we discussed during the meet and confer, Relator takes the position that there does not need to be a causal link between Janssen’s provision of an IOI support service and an account’s claim for payment for the claim to be false. Under this theory, if Janssen provided one or more IOI support services to a Phase One Account and that account

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 6

subsequently wrote prescriptions for Remicade or Simponi ARIA, all claims for prescriptions and associated infusion services are false, and no proof of causation is needed in order to establish False Claims Act liability.

Please confirm that our understanding of your position is correct, and verify that your position is that under the False Claims Act, proof of causation is not required to establish the falsity of claims post-dating a violation of the Anti-Kickback Statute. Please also confirm that you do not intend to rely on any alternative theory of what constitutes a false claim in the event that the Court disagrees with your legal position that all claims submitted after a kickback are “false” and that the False Claims Act requires no causal link between an AKS violation and a false claim. If Relator refuses to disclose an alternate theory of causation and identify the allegedly false claims under that theory, Defendant will seek to preclude her from relying on an alternative causation theory in the future.

Please amend your response to specifically identify the false claims that you allege Defendant caused the Phase One Accounts to submit to Medicare for the reimbursement of Remicade and Simponi ARIA, which cannot be gleaned from the data to which you cite. If your position is that you do not intend to offer proof of causation because it is not legally required, please state so plainly. Finally, please plainly state any alternative theories of causation you will pursue if the Court determines that you are required to prove causation, including the false claims that you allege that Janssen caused the Phase One Accounts to submit based on any alternative causation theories.

Interrogatory 13: State the basis for Your contention that the claims identified in Your response to Interrogatory No. 12 were False Claims.

Your response to Interrogatory 13 does not comply with Local Rule 26.5(c)(8). You need to identify every document, communication, act or omission, and additional fact that is a source for your allegation that the claims were false. Your response does not identify any documents or communications and does not provide any citations.

For example, your response in (a) states that the claims were false because they included items or services “resulting from” an AKS violation (which is inconsistent with your response to Interrogatory 12, where you suggest that no causation is required). If your position is that the claims “resulted from” Janssen’s provision of IOI support services, you are required to provide all of the documents, communications, and facts that make up the basis for that contention.

In addition, your response in (b) refers to a “claim” in which health care providers allegedly made false representations to Medicare, but you do not identify or cite to the specific claim you are referring to. Similarly, your response in (c) refers to certifications made by health care providers in their provider enrollment agreements with Medicare, but you do not identify or cite to the specific certifications or agreements. Furthermore, the response implies that Relator intends to argue that health care providers knew that the IOI support services were illegal kickbacks and nonetheless certified their compliance with the AKS.

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 7

Please provide more detail on the claims and certifications you refer to in your response, including by pointing us to the Bates numbers of any claim forms or certifications that support your allegations. Please also confirm whether you allege that health care providers knew that the IOI support services were illegal kickbacks, or that they were otherwise unlawful, when they certified their compliance with the AKS. In addition, please amend your response to include all of the information required by Local Rule 26.5(c)(8).

Interrogatory 14: State the basis for Your contention in Count I, as it relates to the Phase One Accounts, that Defendant “caused the health care providers to present claims for reimbursement to Medicare . . . that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.”

Your response to Interrogatory 14 does not comply with Local Rule 26.5(c)(8). You are required to identify every document, communication, act or omission, and additional fact that is a source for your contention that Janssen caused the health care providers to present false claims for reimbursement. Instead, you simply describe your contention and direct us to the allegations in your complaint and other interrogatory responses. Likewise, you provide none of the required detail concerning your contention that the “providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.”

Please amend your response to include all of the information required by Local Rule 26.5(c)(8).

Interrogatory 15: State the basis for Your contention in Count II, as it relates to the Phase One Accounts, that “Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare.”

Your response to Interrogatory 15 does not comply with Local Rule 26.5(c)(8). You are required to identify every document, communication, act or omission, and additional fact that is a source for your contention that Janssen caused the health care providers to make false records or statements. Instead, you simply describe your contention and direct us to the allegations in your complaint and other interrogatory responses.

Please amend your response to include all of the information required by Local Rule 26.5(c)(8).

Interrogatory 16: State the basis for Your contention in Counts I and II that the United States was “unaware” that Janssen provided in-office infusion support services.

Your response to Interrogatory 16 does not answer the question asked. Interrogatory 16 asks Relator to state the basis for her contention in Counts I and II that the United States was “unaware” that Janssen provided “in-office infusion support services.” The response provided to Interrogatory 16 states that Ms. Long is unaware of evidence that the United States was aware of the “alleged circumstances and conduct” underlying the complaint. Please amend the response to answer the specific question posed by the interrogatory.

COVINGTON

Casey M. Preston
Theodore J. Leopold
February 24, 2023
Page 8

We note that Relator's counsel has made several statements and inquiries about the scope of the 2003 Department of Justice investigation of Janssen, which resulted in the production of marketing materials to DOJ that identified many of the in-office infusion support services at issue in this matter. As we raised on the meet and confer call, if, for example, the government identified to you or Relator that it was aware of the at-issue programs due to the 2003 investigation, that would be pertinent to Relator's response to the interrogatory. We understand your position is that communications between Relator's counsel and the government are privileged. However, if Relator has relevant knowledge responsive to this interrogatory based on those communications that she is withholding on the basis of privilege, she must assert such a privilege claim in her response.

If Relator had no evidence that the United States was aware that Janssen provided IOI support services before filing this lawsuit, please amend the response to make that clear.

Interrogatory 17: Identify any party or entity holding a contingency interest in the outcome of this case (excluding any arrangement with counsel).

Your response to Interrogatory 17 does not answer the question asked. We asked you to identify any entity holding a contingency interest in the outcome of the case. Instead, you state that Ms. Long is the only relator in the action. As you know, Janssen is obviously aware of that fact. What Janssen does not know—and what this interrogatory asked—is whether there is any entity holding a contingency interest in the outcome of this case.

Your objection that the information sought is not relevant to any claim or defense asserted in the action is not a sufficient basis for refusing to answer the interrogatory. The involvement of, and any communications with, a litigation funder or other party involved in bringing this case are relevant because they could support or undermine the veracity of Ms. Long's allegations. They are, for example, no less relevant than Janssen's communications with DOJ about discovery. And they are certainly discoverable.

Please amend your response to identify any entity holding a contingency interest in the outcome of the case, or explicitly state that no such entity exists (other than Ms. Long and counsel).

Interrogatory 18: Explain, in detail, all information that You provided to the Government, either in writing or orally, before filing this action.

Your response to Interrogatory 18 is sufficient. We appreciate your assertion during the meet and confer that the October 14, 2016 call with AUSA Gregg Shapiro was the only oral communication you or Relator had with the government before filing this action. Please confirm that is the case.

Sincerely,

/s/ Nicholas Pastan
Nicholas Pastan